DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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December 12, 2014

Diagnostica Stago
Ms. Marie Compagnon-Riobe
Registration & Reagent Documentation Manager
125 Avenue Louis Roche
92230 Gennevilliers, France

Re: k142132
Trade/Device Name: Pool Norm Plasma
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: II
Product Code: GGN
Dated: November 4, 2014
Received: November 6, 2014

Dear Ms. Compagnon-Riobe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the

electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulations (21 CFR Parts 801 and 809), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Maria M. Chan -S

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of In Vitro Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142132

Device Name

POOL NORM

Indications for Use *(Describe)*

The Pool Norm is a normal human plasma pool intended for use as a normal control for the activated partial thromboplastin time (APTT) and dilute Russell's viper venom time (dRVVT) assays carried out with the following tests:
– APTT: STA® - PTT A (REF 00595) on STA-R®, STA Compact® and STA Satellite® analyzers
– dRVVT: STA® - Staclot® dRVV Screen (REF 00339, 00333), STA® - Staclot® dRVV Confirm (REF 00334) on STA-R® and STA Compact® analyzers.
This reagent is to be used in clinical laboratories by certified medical laboratory personnel. For in vitro diagnostic use only. For prescription use.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

Submitter's Information: Diagnostica Stago S.A.S.
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France

Contact Person: Marie Compagnon-Riobé
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Date Prepared: December 12th, 2014

Device Name: Pool Norm

Device Classification: Class II
Regulation Number: 21 CFR 864.5425
Panel: Hematology (81)
Product Code: GGN

Predicate Devices: - Pooled Normal Plasma - Pre-amendment device
George King Bio-Medical, INC
- STA® - Control LA 1 - K061803
Diagnostica Stago

Device Intended Use: The Pool Norm is a normal human plasma pool intended for use as a normal control for the activated partial thromboplastin time (APTT) and dilute Russell's viper venom time (dRVVT) assays carried out with the following tests:

– APTT: STA® - PTT A (REF 00595) on STA-R®, STA Compact® and STA Satellite® analyzers

– dRVVT: STA® - Staclot® dRVV Screen (REF 00339, 00333), STA® - Staclot® dRVV Confirm (REF 00334) on STA-R® and STA Compact® analyzers.

This reagent is to be used in clinical laboratories by certified medical laboratory personnel. For *in vitro* diagnostic use only. For prescription use.

Device Description: Pool Norm is a lyophilized pool of at least 20 citrated normal human plasmas, containing buffer, stabilizers and preservatives.

Summary of precision performance data

Repeatability/Within- Laboratory Precision Study was performed in-house according to the CLSI guideline document EP05-A2 (3). Pool Norm was tested for 20 days, 2 runs per day.
Test data are presented below:

- on STA-R®

Assay	Sample Pool Norm Lot	N	X (sec)	Repeatability		Within-Laboratory Precision	
				SD (sec)	CV (%)	SD (sec)	CV (%)
STA® - PTT A	110150	80	33.1	0.3	1.0	0.6	1.7
	110795		32.6	0.3	1.0	0.5	1.6
	111289		32.5	0.3	0.9	0.5	1.5
STA® - Staclot® dRVV Screen	110150	80	42.4	0.3	0.8	0.6	1.4
	110795		41.6	0.2	0.6	0.5	1.3
	111289		41.2	0.2	0.4	0.5	1.1
STA® - Staclot® dRVV confirm	110150	80	38.2	0.3	0.8	0.5	1.3
	110795		37.9	0.3	0.8	0.5	1.3
	111289		37.7	0.3	0.7	0.4	1.1

- on STA Compact®

Assay	Sample Pool Norm Lot	N	X (sec)	Repeatability		Within-Laboratory Precision	
				SD (sec)	CV (%)	SD (sec)	CV (%)
STA® - PTT A	110150	80	33.0	0.5	1.6	0.7	2.1
	110795		32.7	0.4	1.2	0.6	1.7
	111289		32.5	0.5	1.5	0.7	2.1
STA® - Staclot® dRVV Screen	110150	80	40.5	0.3	0.7	0.6	1.6
	110795		40.0	0.3	0.7	0.6	1.4
	111289		39.4	0.4	0.9	0.7	1.8
STA® - Staclot® dRVV confirm	110150	80	37.0	0.3	0.9	0.5	1.4
	110795		36.5	0.5	1.4	0.7	1.9
	111289		36.4	0.4	1.0	0.5	1.4

- on STA Satellite®

Assay	Sample Pool Norm Lot	N	X (sec)	Repeatability		Within-Laboratory Precision	
				SD (sec)	CV (%)	SD (sec)	CV (%)
STA® - PTT A	110150	80	33.5	0.1	0.4	0.3	0.9
	110795		33.1	0.1	0.2	0.3	0.9
	111289		33.1	0.1	0.3	0.3	0.9

Substantial Equivalence Comparison Table:

Attributes or Characteristics	**Pool Norm (Diagnostica Stago) Subject device**	**Pooled Normal Plasma (George King Bio-Medical) Predicate device**	**STA® - Control LA 1 (Diagnostica Stago) Predicate device**
Intended Use	Normal control for the activated partial thromboplastin time (APTT) and dilute Russell's viper venom time (dRVVT) assays carried out with the following tests: – APTT: STA® - PTT A (REF 00595) on STA-R®, STA Compact® and STA Satellite® analyzers – dRVVT: STA® - Staclot® dRVV Screen (REF 00339, 00333), STA® - Staclot® dRVV Confirm (REF 00334) on STA-R® and STA Compact® analyzers. This reagent is to be used in clinical laboratories by certified medical laboratory personnel. For *in vitro* diagnostic use only. For prescription use.	Control plasma intended to be used to monitor coagulation tests. For *in vitro* diagnostic use only.	Lupus anticoagulant (LA) negative plasma intended for the quality control of the tests for LA detection carried out with the following tests: – STA® - Staclot® dRVV Screen (REF 00339, 00333) – STA® - Staclot® dRVV Confirm (REF 00334) – Staclot® LA (REF 00600, 00594). For *in vitro* diagnostic use only.
Assay values reporting	Lot-specific Certificate of analysis: - reporting assay values for Activated Partial Thromboplastin Time (APTT), - certifying negative testing for lupus anticoagulant.	Lot-specific Certificate of analysis: - reporting assay values for Prothrombin Time (PT), Activated Partial Thromboplastin Time (APTT), Fibrinogen, Factors V, VII, VIII, IX, X, XI and XII	Lot-specific Certificate of analysis: - reporting control values for STA® - Staclot® dRVV Screen, STA® - Staclot® dRVV Confirm and Staclot® LA
Test procedure	Same manner as patients' samples	Same	Automatically used by the instruments
Matrix	Pooled citrated human plasma from normal donors	Same	LA negative citrated human plasma
Form	Lyophilized	Frozen	Lyophilized

Attributes or Characteristics	Pool Norm (Diagnostica Stago) Subject device	Pooled Normal Plasma (George King Bio-Medical) Predicate device	STA® - Control LA 1 (Diagnostica Stago) Predicate device
In-use stability	8 hours at 20 ± 5 °C	2 hours after being thawed at 37 °C	*8 hours at 20 ± 5 °C *8 hours on the STA Compact® and STA-R®
Anatomical Sites	Not applicable. No direct patient contact	Same	Same
Storage	2-8 °C	≤ - 70 °C	2-8 °C
Sterility	No sterility requirements. No direct patient contact	Same	Same
Biocompatibility	No biocompatibility requirements. No direct patient contact	Same	Same
Chemical Safety	No issues regarding chemical safety due to no direct patient contact	Same	Same